

IN THE CLAIMS:

Claims 1 – 63 (Cancelled).

64. (Currently amended) ~~A process for the use of devazepide in the manufacture of a monophasic pharmaceutical composition comprising a therapeutically effective amount of devazepide comprising the steps of:~~

a) providing a therapeutically effective amount of devazepide that is sufficient to deliver a daily dosage of devazepide of up to 0.7 mg/kg/day;

b) providing and a suitable amount of a pharmaceutically acceptable surfactant;
and

c) combining the devazepide and the surfactant so as to obtain the monophasic pharmaceutical composition wherein the daily dosage of devazepide is up to 0.7 mg/kg/day.

Claims 65 – 128 (Cancelled).

129. (New) The process of claim 64, wherein the daily dosage of devazepide is from 25 µg/kg/day to 0.7 mg/kg/day.

130. (New) The process of claim 129, wherein the daily dosage of devazepide is from 50 µg/kg/day to 0.5 mg/kg/day.

131. (New) The process of claim 64, wherein the composition is in a liquid form.

132. (New) The process of claim 64, wherein the composition is in a solid dosage form.

133. (New) The process of claim 132, wherein the composition is in the form of a tablet.

134. (New) The process of claim 132, wherein the composition is in the form of a flowable powder in a capsule.

135. (New) The process of claim 64, wherein the opioid is selected from the group consisting of morphine, naloxone, meperidine, butorphanol, pentazocine, morphine-6-glucuronide, codeine, dihydrocodeine, diamorphine, dextropropoxyphene, pethidine, fentanyl, alfentanil, alphaprodine, buprenorphine, dextromoramide, diphenoxylate, dipipanone, heroin, hydrocodone, hydromorphone, levorphanol, meptazinol, methadone, metopon, nalbuphine, oxycodone, oxymorphone, phenadoxone, phenazocine, remifentanil, tramadol, and salts thereof.

136. (New) The process of claim 135, wherein the opioid is selected from the group consisting of hydromorphone, oxycodone, morphine, fentanyl, and salts thereof.

137. (New) The process of claim 136, wherein the opioid is morphine or morphine sulphate.

138. (New) The process of claim 135, wherein the opioid is fentanyl, or a salt thereof.

139. (New) The process of claim 64, wherein the surfactant is a lipophilic surfactant, a hydrophilic surfactant, a glyceride, or a combination thereof.

140. (New) The process of claim 139, wherein the surfactant is a hydrophilic surfactant.

141. (New) The process of claim 140, wherein the hydrophilic surfactant is an ionic or a non-ionic surfactant.

142. (New) The process of claim 141, wherein the hydrophilic surfactant is a non-ionic surfactant selected from the group consisting of alkylglucosides;

alkylmaltosides; alkylthioglucosides; lauryl macrogolglycerides; polyoxyethylene alkyl ethers; polyoxyethylene alkylphenols; polyethylene glycol fatty acids esters; polyethylene glycol glycerol fatty acid esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; polyglycerol fatty acid esters; polyoxyethylene glycerides; polyoxyethylene sterols, derivatives, and analogues thereof; polyoxyethylene vegetable oils; polyoxyethylene hydrogenated vegetable oils; reaction mixtures of polyols and at least one member of the group consisting of fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols; tocopherol polyethylene glycol succinates; sugar esters; sugar ethers; sucroglycerides; and mixtures thereof.

143. (New) The process of claim 141, wherein the hydrophilic surfactant is an ionic surfactant selected from the group consisting of alkyl ammonium salts; bile acids and salts, analogues, and derivatives thereof; fatty acid derivatives of amino acids, camitines, oligopeptides, and polypeptides; glyceride derivatives of amino acids, oligopeptides, and polypeptides; acyl lactylates; mono-, diacetylated tartaric acid esters of mono-, diglycerides; succinoylated monoglycerides; citric acid esters of mono-, diglycerides; alginate salts; propylene glycol alginate; lecithins and hydrogenated lecithins; lysolecithin and hydrogenated lysolecithins; lysophospholipids and derivatives thereof; phospholipids and derivatives thereof; salts of alkylsulphates; salts of fatty acids; docusate sodium; and mixtures thereof.

144. (New) The process of claim 139, wherein the surfactant is a lipophilic surfactant.

145. (New) The process of claim 144, wherein the lipophilic surfactant is selected from the group consisting of alcohols; polyoxyethylene alkylethers; fatty acids; bile acids; glycerol fatty acid esters; acetylated glycerol fatty acid esters; lower alcohol fatty acids esters; polyethylene glycol fatty acid esters; polyethylene glycol glycerol fatty acid esters; polypropylene glycol fatty acid esters; polyoxyethylene glycerides; lactic acid derivatives of mono/diglycerides; propylene glycol diglycerides; sorbitan fatty acid

esters; polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; transesterified vegetable oils; sterols; sterol derivatives; sugar esters; sugar ethers; sucroglycerides; polyoxyethylene vegetable oils; polyoxyethylene hydrogenated vegetable oils; reaction mixtures of polyols and at least one member of the group consisting of fatty acids, glycerides, vegetable oils, hydrogenated vegetable oils, and sterols; and mixtures thereof.

146. (New) The process of claim 139, wherein the surfactant is a glyceride.

147. (New) The process of claim 146, wherein the glyceride is selected from the group consisting of vegetable oils, fish oils, animal fats, hydrogenated vegetable oils, partially hydrogenated vegetable oils, synthetic triglycerides, modified triglycerides, fractionated triglycerides, and mixtures thereof.

148. (New) The process of claim 64, wherein the surfactant is selected from the group consisting of alkyl sulposuccinates, alkyl sulphates and alkyl ammonium salts.

149. (New) The process of claim 148, wherein the surfactant is selected from the group consisting of docusate sodium (dioctyl sodium sulposuccinate), sodium dodecyl sulphate and tetradecyltrimethyl ammonium bromide.

150. (New) The process of claim 64, wherein the composition further comprises one or more fillers selected from the group consisting of lactose, mannitol, talc, magnesium stearate, sodium chloride, potassium chloride, citric acid, spray-dried lactose, hydrolysed starches, starch, microcrystalline cellulose, celluloses, sorbitol, sucrose, sucrose-based materials, icodextrin, calcium sulphate, dibasic calcium phosphate, dextrose and mixtures thereof.

151. (New) The process of claim 150, wherein the composition comprises an amount of devazepide of 1.25 mg, an amount of surfactant of 0.1 mg and 148.65 mg, of a filler.

152. (New) The process of claim 150, wherein the composition comprises an amount of devazepide of 2.5 mg, an amount of surfactant of 0.2 mg and 297.3 mg of a filler.